## Program Information

<table>
<thead>
<tr>
<th>Program Number</th>
<th>2019 P 1078-14</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program</td>
<td>Prior Authorization/Notification - Anticonvulsants</td>
</tr>
<tr>
<td>Medication</td>
<td>Aptiom (eslicarbazepine acetate); Banzel (rufinamide); Briviact (brivaracetam), Diacomit (stiripentol), Epidiolex (cannabidiol), Fycompa (perampanel); Onfi (clobazam); Sabril (vigabatrin), Sympazan (clobazam)*, Vimpat (lacosamide)</td>
</tr>
<tr>
<td>Effective Date</td>
<td>8/1/2019; Oxford: 8/1/2019</td>
</tr>
</tbody>
</table>

### 1. Background:

Aptiom (eslicarbazepine acetate) and Vimpat (lacosamide) are indicated as monotherapy or adjunctive therapy in the treatment of partial-onset seizures.

Banzel (rufinamide), Onfi (clobazam), and Sympazan (clobazam)* are indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS). There is some clinical evidence to support the use of clobazam for refractory partial onset seizures.

Briviact (brivaracetam) is indicated for the treatment of partial-onset seizures.

Diacomit (stiripentol) is indicated for seizures associated with Dravet syndrome in patients taking clobazam.

Epidiolex (cannabidiol) is indicated for seizures associated with Lennox-Gastaut syndrome or Dravet syndrome.

Fycompa (perampanel) is indicated for the treatment of partial-onset seizures with or without secondarily generalized seizures and as adjunctive therapy for the treatment of primary generalized tonic-clonic seizures.

Sabril (vigabatrin) is indicated as adjunctive therapy for refractory complex partial seizures in patients who have inadequately responded to several alternative treatments and for infantile spasms for whom the potential benefits outweigh the risk of vision loss.

Adjunctive therapy is defined as treatment administered in addition to another therapy. Coverage will not be provided for Banzel, or Briviact as primary treatment.

© 2019 UnitedHealthcare Services, Inc.
2. **Coverage Criteria:**

A. **Initial Authorization**

1. **Aptiom** or **Vimpat** will be approved based on one of the following criteria:
   
   a. Diagnosis of partial-onset seizures
   b. For continuation of prior therapy for a seizure disorder

   **Authorization will be issued for 12 months.**

2. **Banzel** will be approved based on one of the following criteria:
   
   a. **All** of the following:
      i. Diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS)
      ii. Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment.)
      iii. Not used as primary treatment

   -OR-
   
   b. For continuation of prior therapy for a seizure disorder

   **Authorization will be issued for 12 months.**

3. **Fycompa** will be approved based on one of the following criteria:
   
   a. **One** of the following:
      i. Diagnosis of partial-onset seizures with or without secondarily generalized seizures

   -OR-
   
   ii. **All** of the following:
      (a) Diagnosis of primary generalized tonic-clonic seizures
      (b) Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment.)
      (c) Not used as primary treatment

   -OR-
b. For continuation of prior therapy for a seizure disorder

**Authorization will be issued for 12 months.**

4. **Briviact** will be approved based on **ONE** of the following criteria:

a. Diagnosis of partial onset seizures

- **OR-**

b. For continuation of prior therapy for a seizure disorder

**Authorization will be issued for 12 months.**

5. **Onfi** or **Sympazan*** will be approved based on **ONE** of the following criteria:

a. **ALL** of the following:
   i. **ONE** of the following:
      (a) Diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS)
      (b) Diagnosis of refractory partial onset seizures (four or more uncontrolled seizures per month after an adequate trial of at least two antiepileptic drugs)

- **AND-**

ii. **BOTH** of the following:
    (a) Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment.)
    (b) Not used as primary treatment

- **OR-**

b. For continuation of prior therapy for a seizure disorder

**Authorization will be issued for 12 months.**

6. **Sabril** will be approved based on **ONE** of the following criteria:

a. **ALL** of the following:
   i. Diagnosis of partial-onset seizures
   ii. Used as adjunctive therapy (defined as accessory treatment used
in combination to enhance primary treatment.)

iii. Not used as primary treatment
iv. Patient has had inadequate response to several (at least three)
alternative anticonvulsants

-OR-

b. Diagnosis of infantile spasms

-OR-

c. For continuation of prior therapy for a seizure disorder

Authorization will be issued for 12 months.

7. Diacomit will be approved based on ONE of the following criteria:

   a. Diagnosis of Dravet syndrome and currently taking clobazam

-OR-

   b. For continuation of prior therapy for a seizure disorder

Authorization will be issued for 12 months.

8. Epidiolex will be approved based on ONE of the following criteria:

   a. Diagnosis of Lennox-Gastaut syndrome or Dravet syndrome

-OR-

   b. For continuation of prior therapy for a seizure disorder

Authorization will be issued for 12 months.

B. Reauthorization

1. Aptiom, Banzel, Briviact, Diacomit, Epidiolex, Fycompa, Onfi, Sabril, Sympazan* or Vimpat will be approved based on the following criterion:

   a. Documentation of positive clinical response to therapy.
Authorization will be issued for 12 months.

3. **Additional Clinical Programs:**
   - *Typically excluded from coverage.
   - Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. **References:**
<table>
<thead>
<tr>
<th>Date</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/2013</td>
<td>Revised diagnosis of Banzel to “Diagnosis of seizures associated with”. Removed age edit from Vimpat and Potiga.</td>
</tr>
<tr>
<td>2/2014</td>
<td>Added Fycompa to criteria.</td>
</tr>
<tr>
<td>5/2014</td>
<td>Added Aptiom to criteria. Revised program name to “Adjunctive Anticonvulsants”</td>
</tr>
<tr>
<td>10/2014</td>
<td>Updated Vimpat criteria to reflect new monotherapy indication. Changed program name to “Anticonvulsants”</td>
</tr>
<tr>
<td>2/2015</td>
<td>Added Onfi to Anticonvulsant guideline. (Onfi previously in 1073, moved to 1078.)</td>
</tr>
<tr>
<td>8/2015</td>
<td>Updated Fycompa criteria and background to reflect new indication for adjunctive therapy for primary generalized tonic-clonic seizures. Updated references.</td>
</tr>
<tr>
<td>10/2015</td>
<td>Updated Aptiom criteria to allow for new indication of monotherapy for partial-onset seizures. Updated references.</td>
</tr>
<tr>
<td>10/2016</td>
<td>Added Briviact to criteria. Administrative changes.</td>
</tr>
<tr>
<td>4/2017</td>
<td>Added Sabril to criteria. Updated requirements for Potiga to include inadequate response to prior therapy. Updated Onfi to include coverage for refractory partial onset seizures. Added criteria for continuation of therapy for all medications. Updated references.</td>
</tr>
<tr>
<td>10/2017</td>
<td>Updated Fycompa criteria to reflect new monotherapy indication. Removed Potiga due to market removal.</td>
</tr>
<tr>
<td>7/2018</td>
<td>Updated Briviact criteria to allow for new indication of monotherapy for partial-onset seizures. Updated references.</td>
</tr>
<tr>
<td>12/2018</td>
<td>Administrative change to add statement regarding use of automated processes.</td>
</tr>
<tr>
<td>3/2019</td>
<td>Sympazan added to criteria.</td>
</tr>
<tr>
<td>5/2019</td>
<td>Diacomit and Epidiolex added to criteria.</td>
</tr>
</tbody>
</table>